INDIANA UNIVERSITY SOUTHEAST INSTITUTIONAL REVIEW BOARD (IRB) REVIEW

NONCOMPLIANCE REPORTING FORM

This form should only be used to report **observed or apparent noncompliance**. **Noncompliance** is defined as any action or activity associated with the conduct or oversight of research involving human subjects that fails to comply with federal or state regulations or institutional policies governing human subjects research or the requirements or determinations of the IRB. Examples include, but are not limited to, failure to obtain IRB approval, inadequate supervision, failure to follow recommendations made by the IRB, failure to report unanticipated problems or protocol changes, etc. This is different from a protocol deviation, which is an alteration/modification to the IRB-approved ***protocol*** that is not approved by the IRB prior to its initiation or implementation. If you need to report a ***major*** protocol deviation, please use the Unanticipated Problems Prompt Reporting Form.

Additional Requirements

1. If this report applies to multiple studies, complete a form for each study.
2. Attach any supporting documentation to the report.

SECTION I: INVESTIGATOR INFORMATION

Principal Investigator:_____**IRB Study Number:**_____

Building/Room No.:_____Department: _____

Phone:_____Fax Number:_____E-Mail:_____

Contact Information:

Name:_____Address:_____Phone:_____

Fax:_____E-Mail:_____

Project Title:

Sponsor/Funding Agency:_____

SECTION II: NONCOMPLIANCE INFORMATION

1. Provide an explanation of the facts surrounding the noncompliance, including a timeline of occurrence of noncompliance and discovery.

2. Provide an assessment of the increased risk (if any) to subjects resulting from the noncompliance.

3. Explain the corrective measures taken in response to the noncompliance and explain any preventive measures that will be taken to prevent the noncompliance from occurring in the future (if possible).

* Please attach any supporting documentation, such as an audit or monitoring report, etc.

SECTION III: INVESTIGATOR ACTION

Please indicate any actions that will be taken as a result of this report:

1. ☐ The informed consent process/document will be revised. Please submit an amendment requesting the revisions. If the amendment cannot be submitted at this time (e.g. requires sponsor approval first), please explain:

2. ☐ The protocol will be revised. Please submit an amendment requesting the revisions. If the amendment cannot be submitted at this time (e.g. requires sponsor approval first), please explain:

3. ☐ Currently enrolled subjects will be notified. Please attach a copy of the notification.

4. ☐ Other corrective and/or preventive action will be taken. Please explain:

5. ☐ The event compromised the validity of the data. Please explain:

Statement of Principal Investigator. I have personally reviewed this report and agree with the above assessment.

Signature of Principal Investigator:_____Date:_____

FOR IRB OFFICE USE ONLY

☐ 1. Report reviewed by IRB Chair or designee.

☐ Report does **NOT** represent noncompliance. Sign report and return to investigator.

☐ Report represents **MINOR** noncompliance. Sign report, return to investigator, and report to IRB.

☐ Report likely represents serious or continuing noncompliance. **Refer to convened IRB**.

Comments/Additional Action:_____
_____
_____

IRB Chair or designee signature:_____Date:_____

☐ 2. Report sent to convened IRB for review. See IRB meeting minutes for additional information.

☐ The report represents **SERIOUS** or **CONTINUING** noncompliance.

☐ The report does **NOT** represent serious or continuing noncompliance.

IRB Signature:_____Date:_____

Recorded in the Minutes of: _____
_____